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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,188	02/12/2004	Peter James Jenkins	08505.0020	3089

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EXAMINER	
PESELEV, ELLI	
ART UNIT	**PAPER NUMBER**
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/776,188	JENKINS ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-24,26-29 and 39-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,11-24,26-29 and 39-41* is/are rejected.

7)☒ Claim(s) *9 and 10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 8, 11-24, 26-29 and 39-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of diabetes with Gibberellin A3 and Gibberellin A3 and A4/A7 mixture, does not reasonably provide enablement for the treatment of diabetes with Gibberellins of Formula (1). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The nature of the invention.

Drug discovery is one of the most labor intensive and expensive types of inventions; it can cost over $500 million to bring a single new drug to market.

(B) The state of the prior art.

The art is unaware of successful treatment of diabetes with chemically analogous compounds.

(C) The predictability or lack thereof in the art.

"In applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims" (see MPEP 2164.03). In the present case, the specification presents data showing the effect on blood glucose levels of Gibberellin A3. Based on the

evidence of activity limited to Gibberellin A3, it cannot be predicted what other Gibberellins having diverse structural formulas encompassed by the present claims will have similar effect on blood glucose levels as Gibberellin A3.

(D) The amount of direction or guidance present.

The specification discloses a single specific compound and said compound with A4/A7 mixture which has a blood sugar lowering activity. However, this guidance is not commensurate with the full scope of the claims.

(E) Breadth of the claims.

The claims encompass an immense number of species having significant differences in structural formulas. For example, a compound of Formula (1) wherein R1, R2, R3, R4, R5, R6, R7, R8, R9, R10 and R11 are hydrogens is significantly different structurally from the compound of Formula (I) wherein R1 , R2, R3, R5, R7, R8 and R10 are glycosylic ether groups, R4 is C20 alkyl, R6 and R10 are hydroxy groups.

(F) The quantity of experimentation needed.

Because there is no way to predict a priori which compounds will be active from the specification or chemical structures alone, an extraordinary amount of trial and error experimentation is required to identify the active compounds.

Applicant's arguments filed December 12, 2006 have been fully considered but they are not persuasive.

Applicant contends that the examiner has neglected to consider the disclosed Gibberellin A 4 and A7. This argument has not been found persuasive. The specification fails to disclose treatment of diabetes with Gibberellin A4 or A7 but

discloses the treatment of diabetes with a mixture of Gibberellin A3 with Gibberellin A4 and/or A7. Further note that Gibberellins A3, A4 and A7 have closely related structural formulas (see columns 1-2 of the U.S. Patent No. 6,287,800). However, the present claims encompass compounds having major variations in structural formulas. For example, R1 together with R2 forms a double bond in the structural formulas for Gibberellins A3 and A7 and in Gibberellin A4, R1 and R2 are hydrogens. However, the present claims encompass compounds wherein R1 is hydroxyl, glycoside ether or alkyl ether and R2 is a glycoside ether. The present claims encompass an immense number of species. The disclosure of three specific species having closely related structural formulas is not commensurate with the full scope of the claimed invention.

Claims 9 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev

ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200